

Do I still want to take this? Soll ich das wirklich schlucken?

Uncertainty avoidance in English and German PILs - a contrastive study

Aim and focus

The current study aims to compare the linguistic means used in German and English patient information leaflets (PILs) for patients' understanding and behaviour concerning medicine intake. We focus on the expression of uncertainty avoidance.

Background

Three studies and a European guideline lie at the basis of the current study. Readability has been an important issue for PILs. However, Clerehan et al. (2005) already made a plea for a linguistic analysis of PILs beyond the level of statistical readability measures as well as the content-level. They applied a systemic-functional framework for the assessment of the quality of Australian PILs for that purpose.

On the European level, the 2009 *European Medicines Agency (EMA)'s Guideline* similarly contains linguistic recommendations (incl. syntax and style). This recommendatory guideline has been elaborated by the different national legislative bodies, including the German *Federal Institute for Drugs and Medical Devices (BfArM)* and the British *Medicines and Healthcare products Regulatory Agency (MHRA)*. It was also critically analyzed in Fuchs and Götze (2009).

Our study is further inspired by van Berkel and Gerritsen's (2012) analysis of intercultural differences between Flemish and Dutch PILs, which is based on Hofstede's (2001) concept of uncertainty avoidance as a cultural value to measure people's behaviour concerning risk management.

Research Question

Hofstede's model describes Germany as a highly uncertainty avoidant culture, as opposed to the United Kingdom. For the current study we will compare the linguistic means for uncertainty avoidance in German and (UK) English PILs, as we believe uncertainty avoidance is particularly relevant for patients' behaviour concerning medicine intake.

Corpus

Our corpus consists of post-2009 PILs issued by BfArM and MHRA, drawn from the EMA-database. We will analyze two specific sections from the leaflets, recognized in the 2009 EMA-Guideline, viz. section 2. *Before you take XYZ* and section 4. *Possible side-effects*, as these contain information which is directly relevant for patients' risk management.

Method

Our contrastive linguistic analysis is based on the above-mentioned frameworks. One field which is crucial with respect to uncertainty avoidance is that of modality (e.g. *X may cause a serious skin rash that may cause you to be hospitalized or even cause death*). Another important domain is the expression of degree (notably expressions of frequency and severity, cf. Fuchs and Götze 2009, and amplifiers, cf. Pahta 2006). Clerehan et al.'s (2005: 337) framework further provides us with useful categories, viz. (i) rhetorical elements (is the reader informed, instructed, advised etc.), (ii) role relationship between writer and reader (who takes responsibility for the action to be undertaken when side-effects occur), and (iii) factual content, notably the source of information and quality or strength of evidence concerning side-effects. Two other key categories from Clerehan et al. are those of the technicality of (medical) vocabulary and lexical density. The latter is also related to explicitation and addition of non-essential information for uncertainty avoidance.

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